

Remarks

Applicants request reconsideration of the above-referenced patent application.

I. Claim Amendments

Withdrawn claims 21-24 have been canceled pursuant to Applicants' election in response to the September 20, 2002 restriction requirement. Claims 36-40 have been added. Thus, claims 1-3, 6-20, and 25-40 are pending. Applicants have amended claims 1-3, 6-8, 13, 14, 18-20, and 25-35. All the pending claims, including the amendments, are shown in the previous section.

Applicants submit that the amendments and new claims do not introduce any new matter.

Specifically:

Claim 27 has been amended to be specifically directed to a drug delivery system of claim 1 for oral administration. This amendment is supported by Applicants' specification at, for example, page 16, lines 1-4; and page 18, lines 8-10.

Claim 28 has been amended to be directed to a method of treatment using a drug delivery system of claim 1. This amendment is supported by Applicants' specification at, for example, page 5, line 29 to page 6, line 1.

Claim 35 has been amended to be directed to a use of a drug delivery system of claim 1 to prepare a medicament. This amendment is supported by Applicants' specification at, for example, page 6, lines 7-13.

Other amendments rephrase the claims, remove redundancies or unnecessary terms, make the dependent claim language more consistent with claim 1 (*i.e.*, the dominant claim), or correct grammatical or obvious errors. Applicants submit that such amendments are permissible under MPEP §2163.07.

New claims 36 and 38 are supported by Applicants' specification at, for example, page 17, line 32 to page 18, line 1.

New claims 37 and 40 are supported by Applicants' specification at, for example, page 18, lines 8-10.

New claim 39 is supported by Applicants' specification at, for example, page 16, lines 1-4; and page 18, lines 8-10.

Applicants reserve the right to pursue any canceled subject matter and/or any other subject matter disclosed in this application in one or more later-filed divisional and/or continuation applications.

II. Response to rejection of claims 1-3, 6-20, and 25-27 under 35 U.S.C. §103(a)

Claims 1-3, 6-20, and 25-27 have been rejected under 35 U.S.C. §103(a) as being obvious in view of WO 96/03113 and Lambert et al. (U.S. Patent No. 6,660,286). Applicants request withdrawal of this rejection.

Claim 1 is directed to a self-emulsifying drug delivery system that comprises an extremely water-insoluble, lipophilic active agent; polyvinylpyrrolidone; a fatty acid; and a surfactant. The Office action relies on WO 96/03113 as teaching self-emulsifying drug delivery systems comprising a water-insoluble active agent, a fatty acid, and a surfactant. The Office action relies on Lambert et al. as teaching the use of polyvinylpyrrolidone in self-emulsifying drug delivery systems.

The subject matter of claim 1 cannot be *prima facie* obvious in view of WO 96/03113 and Lambert et al., whether viewed alone or in combination. For a combination of references to establish a *prima facie* case of obviousness, there must be a motivation to combine their teachings. As noted in MPEP §2143:

[t]o establish a *prima facie* case of obviousness, . . . there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.

There is no such motivation for combining WO 96/03113 with Lambert et al. To the contrary, the teachings in WO 96/03113 and Lambert et al. are contradictory, and therefore teach away from such a combination. Specifically, Lambert et al. repeatedly state that their reported compositions are "substantially ethanol-free." See, e.g., Lambert et al., abstract; col. 4, lines 42-58; and col. 11, lines 58-62. In fact, Lambert et al. expressly state that their reported compositions are "substantially free of any monohydric alcohol." See, e.g., Lambert et al., col. 4, lines 61-63 (emphasis added). WO 96/03113, in contrast, states that its compositions preferably comprise ethanol. See, e.g., WO 96/03113, page 6, lines 1-5 and 24-27; and page 7, line 31 to

page 8, line 3. Given these contradictory teachings, WO 96/03113 and Lambert et al. cannot be combined to support a *prima facie* showing of obviousness as to claim 1. See MPEP §2145(X)(D)(2) ("It is improper to combine references where the references teach away from their combination."). Thus, the rejection of claim 1 must be withdrawn.

All the remaining pending claims depend from claim 1, and are therefore patentable over the cited references for at least the same reasons as claim 1. It should be noted, however, that at least some of these claims also are patentable over the cited references due to the additional limitations that they recite. For example, claims 6 and 18 recite drug delivery systems wherein the concentration of polyvinylpyrrolidone is from 5% to about 40%. Neither WO 96/03113 nor Lambert et al. teach or suggest using such polyvinylpyrrolidone concentrations, particularly in the context of a self-emulsifying drug delivery system. Claims 6 and 18 therefore cannot be *prima facie* obvious in view of WO 96/03113 and Lambert et al. See MPEP §2143 ("[t]o establish a *prima facie* case of obviousness, . . . the prior art reference . . . must teach or suggest all the claim limitations."). If anything, Lambert et al. teach away from such concentrations. Specifically, when discussing polyvinylpyrrolidone, Lambert et al. state "[c]oncentrations up to 5% w/v can be used as a co-solvent for poorly soluble drugs." See, Lambert et al., col. 7, lines 54-55. This further supports the patentability of claims 6 and 18. See MPEP §2145(X)(D)(1) ("A prior art reference that 'teaches away' from the claimed invention is a significant factor to be considered in determining obviousness. . . .").

III. Request for rejoinder of method-of-treatment and use claims once corresponding formulation claims are found to be allowable

Although examination is currently restricted to formulation claims (*i.e.*, claims 1-3, 6-20, 25-27, and new claim 37), Applicants request that the corresponding method-of-treatment claims (*i.e.*, claims 28-34, and new claims 38-40) and use claims (*i.e.*, claim 35 and new claim 36) be rejoined into the application to the extent that such claims have the same limitations as any allowed formulation claims. Under such a circumstance, this rejoinder is required:

Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance.

U.S. Appl. 09/909,691
Amendment C
April 15, 2005

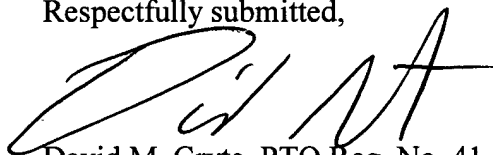
MPEP §821.04 (emphasis added). It should be noted that claims 28-36 and 38-40 all directly or indirectly depend from claim 1, and therefore necessarily include the same limitations as claim 1.

* * * * *

Applicants hereby request a 3-month extension to respond to the November 12, 2004 Office action. Applicants have enclosed a check to cover the fee for the extension. Applicants believe that they do not owe any additional fee in connection with this filing. If, however, Applicants do owe any such fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. **08-0750**. In addition, if there is ever any other fee deficiency or overpayment under 37 C.F.R. §1.16 or 1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. **08-0750**.

Applicants submit that the pending claims are in condition for allowance, and request that this application be allowed. The Examiner is requested to call the Undersigned if any issues arise that can be addressed over the phone to expedite examination of this application.

Respectfully submitted,

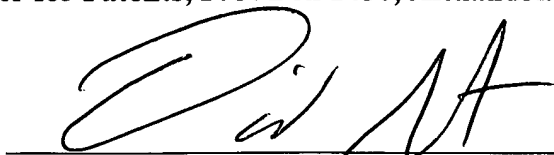
A handwritten signature in black ink, appearing to read 'D. Gryte', is written over the typed name.

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CERTIFICATE OF MAILING UNDER 37 CFR § 1.8

I certify that this correspondence is being deposited with the U.S. Postal Service on **April 15, 2005** with sufficient postage as first class mail (including Express Mail per MPEP §512), and addressed to **Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.**

A handwritten signature in black ink, appearing to read "David A. [unclear]", is written over a horizontal line.

DMG/PML